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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,383	05/26/2000	Joseph M. Vinetz	026.00101	7685

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	7

DATE MAILED: 05/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/579,383	VINETZ, JOSEPH M.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- Th MAILING DATE of this communication appears on th cover she t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *13-22 and 25-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I, claims 1-12, 23 and 24 (DNA) with respect to SEQ.ID.NO: 1 and encoding protein SEQ.ID.NO: 3 in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, claims 13-22, 25-45 have been withdrawn from consideration.

Priority

2. Applicant's priority under 35 U.S.C. 119 (c) to provisional applications 60/136,508 filed on 5/28/1999 and 60/180,051 filed on 2/3/2000 is acknowledged. Applicant gets priority as of 5/28/1999 for claims 4 and 5 with respect to the SEQ.ID.NO: 1 and 3 (Plasmodium falciparum cDNA and protein).

Information Disclosure Statement

3. Information Disclosure Statement has not been filed in this application.

Drawings

4. The drawings are not approved by the draftsperson under 37 C.F.R. 1.84 or 1.152. See PTO-948 for details.

Claim Rejections - 35 USC 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-12, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the interim guidelines on written description published June 15, 1998 in the Federal Register at Volume 63, Number 114, pp 32639-32645 (also available at www.uspto.gov). This is a written Description Rejection.

Claims are drawn to an isolated nucleic acid molecule encoding a Plasmodium Sp chitinase, oligonucleotide complementary to portion of mRNA, expression vectors and host cells comprising the expression vectors. However, the specification discloses only SEQ.ID.NO: 1 that encodes a polypeptide disclosed in SEQ.ID.NO: 3 with regard to recombinant P.falciparum chitinase (see pages 72-73) expression vector, pET32b tranfected into DH10B E.coli host cells. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, SEQ.ID.NO: 1 (with regard to elected invention) is the only species among plasmodium whose complete structure is disclosed.

Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence). In the instant case, the other identifying characteristics are the functional motifs such as secretory signal peptide sequence, substrate binding and catalytic sites of chitinase. Therefore, this limited information disclosed in the specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of cDNAs from all other plasmodium besides SEQ.ID.NO: 1 (plasmodium falciparum, elected invention) at the time the application was filed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus (for example P.vivax, P.malariae, P.ovale, P.

knowlesi and P.berghei etc)) and because the genus is highly variant (for example P.vivax and P.berghei are highly variant to each other) the disclosure of specific nucleotide sequences and the ability to screen is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus (i.e., plasmodium) as broadly claimed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus (i.e., gene). Therefore, this limited information disclosed in the specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of cDNA besides SEQ.ID NO: 1 at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus (i.e., Plasmodim)

7. Since there is no written description support for all plasmodium species, claims 1-12, 23 and 24 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding P.falciparum sporozoite chitinase (SEQ.ID.NO: 1 and expression vector) does not reasonably provide enablement for any and all isolated nucleic acids encoding any and all plasmodium sporozoite chitinases as recited broadly in instant claims.

8. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a P.falciparum sporozoite chitinase polypeptide, said polynucleotide encodes an amino acid sequence as set forth in the SEQ.ID.NO: 3 does not reasonably provide enablement for an isolated polynucleotide encoding P.falciparum chitinase polypeptide, said polynucleotide encoding a first amino acid sequence having at least 90% amino acid identity to a second amino acid sequence, said second amino acid sequence as set forth in the SEQ.ID.NO: 3. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Scope of enablement requires that the specification teach those in the art to make and use the invention commensurate with the scope of the claim without undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

With regard to %identity, the specification is not enabled for polypeptides which have an amino acid 90% sequence identity with SEQ.ID.NO 3 because it is unclear to one skilled in the art what sequences are embraced by the claim. If it is unclear to one skilled in the art what sequences are embraced by a claim which is based on a specification to determine percent identity, the specification is non-enabling, since one skilled in the art would not be able to make and use those sequences without undue experimentation.

The specification provides guidance and direction with regard to an isolated polynucleotide encoding a polypeptide SEQ.ID.NO 3 which is designated as P.falciparum chitinase protein on page 26. However, there is no guidance or directions on how to make and use an isolated polynucleotide encoding a polypeptide, which has an amino acid 90% identity with SEQ.ID.NO 3.

It is well known that for proteins, for example, even a single amino acid change can destroy the function of the biomolecule. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Further, specification is silent on how to make a protein with 90% sequence identity to SEQ.ID.NO: 3. Applicant failed to give direction to what modification have been done to SEQ.ID.NO 3 to give rise to 90% sequence identity to

said polypeptide. What changes would have an adverse effect on the function of this peptide is not predictable. It is known in the art that proteins, which are obtained by substitutions, deletions, or modifications of the amino acids of a protein (in this case protein with 90% identity to SEQ.ID.NO: 3 is considered as a variant), alter the function of the protein. The amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and still retain similar activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, the problem of predicting protein structure from mere sequence data of a single protein and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex (Bowie et al. Science, Vol. 247: 1990; p. 1306; p. 1308) and is well outside the realm of routine experimentation.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed polypeptide in a manner reasonably correlated with the scope of the claims broadly including any number of insertions, deletions or substitutions that would encompass a biologically active variant of a Plasmodium chitinase as presently claimed. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made in the protein renders activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1-12, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 23 are rejected as being vague in reciting " an isolated nucleic acid molecule encoding a Plasmodium sp. Chitinase". Does applicant intend to mean an isolated polynucleotide encoding a Plasmodium species chitinase protein or polypeptide? or Plasmodium sporozoite chitinase protein or polypeptide?

Claim 8 is rejected as being vague and indefinite for the recitation of " at least a portion". It is not clear which portion of mRNA is complementary to the claimed oligonucleotide.

Claim 23 is rejected as being vague and confusing. It is not clear how an isolated nucleic acid molecule (one) encode first and second amino acid sequences?

Claim 24 is rejected as being vague in reciting "capable of. " The term "capable of "renders the claim indefinite since the metes and bounds of the term "capable of " are not defined.

Applicant is advised to amend the claims to recite the sequence identification numbers SEQ.ID.NO: 1 and 3 since the elected invention is drawn to said sequences.

Claim Rejections - 35 USC 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-2 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Sim et al 1989(Molecular and Biochemical Parasitology: 34:127-134).

Claims are drawn to an isolated nucleic acid molecule encoding a Plasmodium sp chitinase and a DNA oligomer capable of hybridizing to the nucleic acid.

With regard to an isolated nucleic acid molecule encoding a Plasmodium sp chitinase, the prior art discloses the nucleic acid molecule encoding chitinase from sporozoites of P. falciparum and P.berghei as the DNA obtained from infected mosquitoes carries sporozoites which would encode chitinase (page 129, right column, lines 1-5). The DNA was denatured and isolated on to the filters (see page 128, left column, first paragraph). DNA oligomer probes namely pPb3, p24B1-1 were hybridized to the nucleic acid (see figure 3 and figure 4). The prior art anticipated the claimed invention.

13. Claims 1-3, 6-12, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Vinetz et al 1999(PNAS: 96:14061-14066).

Claims are drawn to an isolated nucleic acid molecule encoding a Plasmodium sp chitinase; wherein said DNA is cDNA, RNA, mRNA and a DNA oligomer capable of hybridizing to the nucleic acid. Claims are also drawn to oligonucleotide complementary to at least a portion of the mRNA, expression vector and host cells.

Vinetz et al 1999 disclose an isolated nucleic acid molecule encoding plasmodium chitinase (i.e., P.falciparum), wherein said DNA (see abstract) is cDNA, RNA (see page 14062, right column, first paragraph), mRNA (see Figure 2c and Results: characterization of full length Chitinase gene) and a DNA oligomer capable of hybridizing to the nucleic acid (Figure 2).

Plasmid pET32b, which expresses PfCHT1, is complementary to mRNA of the nucleic acid that encodes chitinase and is tranfected into E.coli host cells (see page 14064, left column). Thus, the prior art anticipated the claimed invention with respect to an isolated nucleic acid molecule encoding a Plasmodium sp chitinase.

Status of Claims

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

5/13/02

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